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SECTION 5: 510(K) PREMARKET NOTIFICATION

Summary of Safety and Effectiveness information

Tornier Aequalis™ Ascend™ Flex Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) **Device name**
Trade name: **Aequalis™ Ascend™ Flex Shoulder System**
Common name: Shoulder Prosthesis

Classification Number/ Classification name/Product code:

- Shoulder joint metal/polymer non-constrained cemented prosthesis are class II devices under 21 CFR 888.3650 (product code KWT) and are classified by the Orthopedic Devices Panel
- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS) and are classified by the Orthopedic Devices Panel
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis are class II devices under CFR 888.3690 (product code HSD) and are classified by the Orthopedic Devices Panel

2) **Submitter**
TORNIER SAS
161 rue Lavoisier
38330 Montbonnot Saint Martin- France
Registration Number: 3000931034

3) **Company contact**
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10801 Nesbitt Avenue South
Bloomington, MN 55437

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4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWT; KWS; HSD;

5) **Legally Marketed Device to which Equivalence is Claimed:**

Primary Predicates:

- Tornier Inc. Ascend Shoulder System (K121493; most recent)
- Tornier Inc. Aequalis Ascend Modular Reverse Shoulder System (K112615)

Reference Predicate:

- Tornier Inc. Aequalis® Adjustable Reverse Shoulder System (K120739)

6) **Device description**

The Aequalis Ascend Flex Shoulder System consists of:

- **In a Anatomic configuration:** A titanium humeral stem offered in Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a compatible humeral head (CoCr) with a compatible UHMWPE Aequalis glenoid; or UHMWPE Affiniti Anatomic glenoid. The Aequalis Ascend Flex Shoulder System stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid, as a total shoulder joint replacement.
- **In a Reversed configuration:** a titanium humeral stem offered in Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a reversed adapter with compatible Aequalis Reversed glenoid implants.

  The reversed adapter is comprised of two components: a titanium tray and a UHMWPE reversed insert.

  The Aequalis Reversed glenoid implants is comprised of four components: Baseplate: made from Titanium; Glenoid sphere: made from of CoCr; Screw (baseplate/to glenoid sphere): made from CoCr and Fixation screws: made from Titanium.

The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear.

The present device submission corresponds to modifications made to the version of the device cleared in 510(k) K121493 (most recent) and K112615.

7) Intended and Indications for Use

SYSTEM INTENDED USE:
The Aequalis Ascend Flex Shoulder System is intended for use as:

- A replacement of shoulder joints in primary anatomic or in primary reverse.
- A replacement of other shoulder joints devices in case of revisions if sufficient bone stock remains.
- The Aequalis Ascend Flex Shoulder System also allows for conversions from anatomic to reverse shoulder prosthesis in case of revision.

IN ANATOMIC: The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.
The Aequalis Ascend Flex Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.
The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

IN REVERSE: The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains

The reversed adapter is indicated for use as components of the Aequalis Ascend Flex Shoulder System total shoulder replacement and for transformation of the Aequalis Ascend Flex Shoulder System into a reverse shoulder prosthesis without the removal of the humeral stem during revision surgery for patients with a functional deltoid muscle. The components are permitted to be used in the transformation from anatomic to reverse if the humeral stem is well fixed, the patient has a functional deltoid muscle; the arthropathy is associated with a massive and non-repairable rotator cuff-tear.
Notes:

- All components are single use.
- The coated humeral stem is intended for cemented or cementless use.
- The non-coated humeral stem is intended for cemented use only.
- All poly glenoid components are intended for cemented use only.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.

8) Summary of technologies

The **Aequalis Ascend Flex Shoulder System** was subjected to non-clinical testing such as stem strength evaluation in Anatomic/Reverse configurations; taper evaluation; reverse adapter evaluation; head glenoids mismatch evaluation; system range of motion evaluation; and Titanium Plasma Spray coating validation per FDA guidance. The results of these non-clinical tests allow us to conclude that the **Aequalis Ascend Flex Shoulder System** described in this submission is substantially equivalent and as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Tornier, SAS
% Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Letter dated: January 8, 2013

Re: K122698
Trade/Device Name: Aequalis™ Ascend™ FlexFlex Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: December 7, 2012
Received: December 10, 2012

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122698
Device Name: **Aequalis™ Ascend™ FlexFlex Shoulder System**

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The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

IN REVERSE: The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
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Prescription Use ___X____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices 2013.01.03 15:20:56 -05'00'